

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: ) Art Unit: 1648  
CLASSEN, John B. ) ) Examiner: BRUMBACK, B  
Serial No.: 08/591,651 ) ) Washington, D.C.  
Filed: February 12, 1996 ) ) March 5, 2003  
For: METHOD AND COMPOSITION ) ) Docket No.: CLASSEN=1A  
FOR AN EARLY VACCINE TO ) )  
PROTECT AGAINST BOTH... ) ) Confirmation No.: 9417

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REQUEST FOR RECONSIDERATION AND MODIFICATION OF  
DECISION ON PETITION UNDER 37 CFR §1.181

**HAND CARRY TO GROUP**

Honorable Commissioner of Patents  
Washington, D.C. 20231

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Applicants hereby request that the February 6, 2003 decision on petition be reconsidered, and modified to direct the Examiner to enter and consider the exhibits filed October 18, 2002 which were published after the November 5, 2001 mail date of the final rejection.

Background

In response to the Appeal Brief filed May 1, 2000, the examiner withdrew the finality of the prior office action and reopened prosecution. In the new office action, mailed June 20, 2000, the Examiner entered a new rejection for lack of enablement. This rejection relied on the 1999 "PIDJ" article. Subsequently, in the rejection mailed February 21, 2001, the Examiner "string-cited" DeStafano et al. (ref. DU) (1997); EURODIAB Substudy 2 Study Group (ref. EB) (2000), Graves et al. (ref. EF) (1999), Heijbel, et al. (ref. EI) (1997), Hiltunen et al. (ref. EL) (1999), Jefferson et al. (ref. EQ) (1998), Karvonen et al. (ref. EV) (1999), Bedford H. (ref. HD) (1999), Petousis-Harris et al. (ref. HE) (1999), Dahlquist et al. (ref. HK)

(1995), Jefferson T.O. (ref. HP) (1999), Elliott et al. (ref. IJ) (1998), and Anonymous (ref. IN) (January 30, 2001) on pp. 7-8.

The final rejection was mailed November 5, 2001, and a notice of appeal was filed May 6, 2002. On October 18, 2002, Applicant filed a Declaration under 37 CFR 1.132, with supporting exhibits. The declaration and exhibits were refused entry, and applicants petitioned against this refusal on December 12, 2002.

The following exhibits were published after the final rejection of November 5, 2001, and hence are at issue here:

Sanjeevi, et al., Ann. N.Y. Acad. Sci. 958:293-6 (2002) (cited in Declaration, Table 1, item 8)

Institute of Medicine, The Anthrax Vaccine: Is it safe? Does it work? (March 2002) (selected pages) (Declaration, Table 1, item 9 and Table 2A, item 12)

DeStefano, et al. Pediatrics:108:?? (December 2001) (Declaration, Table 2A, item 8)

Classen and Classen, "Clustering of cases...", Autoimmunity, 35(4):247-53 (2002) (published version of unpublished manuscript submitted August 17, 2001) (Declaration, Table 1, Item 7)

Classen, et al., "Vaccines and the risk of insulin dependent diabetes (IDDM):Potential mechanism of action, Medical Hypotheses (November 2001)<sup>1</sup> (Declaration \$12).

#### Analysis of Decision

The decision on petition was based on 37 CFR 1.195, which states

Affidavits, declarations, or exhibits submitted after the case has been appealed will not be admitted without a showing of

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<sup>1</sup> The publication date is shown in the attached MEDLINE abstract, Ex. A.

good and sufficient reasons why they were not earlier presented.

The PTO denied entry of the "recently published evidence" because, it said, such evidence could not be "used to show enablement". It argued that because of the passage of several years between the filing of the application (1994) and the date of publication of the evidence (2002), the evidence could not be used to show that the specification was enabling. There are several problems with this conclusion.

First, it is inconsistent with judicial authority. In Amgen Inc. v. Hoechst Marion Roussel, Inc., 57 USPQ2d 1449, 1517 (D. Mass. 2001), the district court held that enablement of the '349 patent was demonstrated by a series of postfiling publications, notably Yanagi, Powell and Ohashi. The '349 patent had a November 30, 1984 filing date. The court unfortunately does not provide bibliographic citations, but "Yanagi" is described as having produced human erythropoietin in cultured human cells, which appears to be a reference to one of two 1990 papers (see attached Exhibit B). This use of postfiling evidence was upheld by the Federal Circuit, 2003 U.S. App. LEXIS 118, \*55 (January 6, 2003).

In Gould v. Quigg, 3 USPQ2d 1302 (Fed. Cir. 1987), the interval was even longer; the questioned expert testimony was given in 1985, 26 years after Gould's 1959 filing date.

The testimony was based, but only in part, on a postfiling article, apparently one by Frish and Bochkova, itself published three years after Gould's filing date, see Gould v. Mossinghoff 229 USPQ 1, 6 (D.D.C. 1985).

The district court held that "the fact that Frish's achievement of conditions which would permit laser amplification did not occur until a few years after Gould's filing date was and is of no moment". Id., 8.

Secondly, the decision disregards how the evidence is being

used. If the problem with the specification had been that it left out certain details as to how to practice the invention, and the issue was whether it required undue experimentation to make the appropriate choices, the passage of many years between applicants' teaching and the fulfillment of that teaching by others arguably might be relevant to the adequacy of the teaching. (Although the courts apparently do not agree!) But here, the enablement issue is really a utility issue. The Examiner refuses to accept applicant's human epidemiological data and animal experimental data (in the specification) showing that the timing of immunization affects the incidence of diabetes. She questions the causal relationship inferred by Applicant. It should not matter whether the evidence that Applicant is correct is published a year later, or ten years later; it is still relevant to Applicant's case that the invention is operable.

Thirdly, the PTO's refusal to accept the 2002 articles as evidence, because they are not contemporaneous with the filed application, is particularly unjust in view of the PTO's reliance on references published several years after the filing date, notably the PIDJ (1999) and EURODIAB (2000) publications. Perhaps the more relevant time interval is the one between the reference date and the new exhibit date.

Finally, even if the PTO were correct that the date of the evidence was relevant to its plausibility, that would appear to affect the weight the evidence should be given, and not its admissibility. Given that this case is under appeal, the Group is usurping the function of the Board by using 37 CFR 1.195 to deny the Board the opportunity to consider exhibits which applicant considers relevant and which could not have been presented prior to final rejection because they had not yet been published. This is arbitrary and capricious agency action within the meaning of the Administrative Procedures Act.

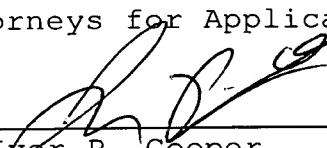
It is believed that no fee is due in connection with this

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request. If we are mistaken, please charge the fee to Deposit Account 02-4035.

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.  
Attorneys for Applicant

By: 

Iver P. Cooper  
Reg. No. 28,005

Enclosures

-Exhibit re Yanagi Citations  
-Exhibit A, re Publication Date of Medical Hypotheses article  
624 Ninth Street, N.W.  
Washington, D.C. 20001  
Telephone: (202) 628-5197  
Facsimile: (202) 737-3528  
IPC:lms  
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